Food and Drug Administration, HHS

culturing and susceptibility tests on samples collected prior to treatment. If no response to chloramphenicol therapy is obtained in 3 to 5 days, discontinue its use and review diagnosis. Not for animals which are raised for production. Chloramphenicol products must not be used in meat-, egg-, or milk-producing animals. The length of time that residues persist in milk or tissues has not been determined. Because of potential antagonism, chloramphenicol should not be administered simultaneously with penicillin or streptomycin. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

- (b)(1) *Specifications*. Each tablet contains 50, 100, 250, or 500 milligrams, or 1 gram of chloramphenicol.
- (2) *Sponsor*. See No. 061623 in §510.600(c) of this chapter.
- (3) Conditions of use. Dogs—(i) Amount. 25 milligrams per pound of body weight every 6 hours.
- (ii) *Indications for use*. Oral treatment of bacterial gastroenteritis associated with bacterial diarrhea, bacterial pulmonary infections, and bacterial infections of the urinary tract caused by susceptible organisms.
- (iii) Limitations. Laboratory tests should be conducted, including in vitro culturing and susceptibility tests on samples collected prior to treatment. If no response is obtained in 3 to 5 days, discontinue use and reevaluate diagnosis. Not for animals that are raised for food production. Chloramphenicol products should not be administered in conjunction with or 2 hours prior to the induction of general anesthesia with pentobarbital because of prolonged recovery. Chloramphenicol should not be administered to dogs maintained for breeding purposes. Because of potential antagonism, chloramphenicol should not be administered simultaneously with penicillin or streptomycin. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37323, Aug. 18, 1992, as amended at 62 FR 35076, June 30, 1997; 66 FR 14073, Mar. 9, 2001; 68 FR 4914, Jan. 31, 2003]

§520.390b Chloramphenicol capsules.

- (a) *Specifications*. Each capsule contains 50, 100, 250, or 500 milligrams (mg) chloramphenicol.
- (b) *Sponsors*. See Nos. 000069 and 050057 in §510.600(c) of this chapter for use as in paragraph (d) of this section.
- (c) Special considerations. Federal law prohibits the extralabel use of this product in food-producing animals.
- (d) Conditions of use in dogs—(1) Amount. 25 mg per pound of body weight every 6 hours.
- (2) Indications for use. For treatment of bacterial pulmonary infections, bacterial infections of the urinary tract, bacterial enteritis, and bacterial infections associated with canine distemper caused by susceptible organisms.
- (3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[70 FR 75398, Dec. 20, 2005, as amended at 73 FR 18442, Apr. 4, 2008; 75 FR 55676, Sept. 14, 2010]

§ 520.390c Chloramphenicol palmitate oral suspension.

- (a) Specifications. Each milliliter contains chloramphenicol palmitate equivalent to 30 milligrams of chloramphenicol.
- (b) Sponsor. See No. 000856 in \$510.600(c) of this chapter.
- (c) Conditions of use. Dogs—(1) Amount. 25 milligrams per pound of body weight every 6 hours. If no response is obtained in 3 to 5 days, discontinue use and reevaluate diagnosis.
- (2) Indications for use. Treatment of bacterial pulmonary infections, infections of the urinary tract, enteritis, and infections associated with canine distemper that are caused by organisms susceptible to chloramphenicol.
- (3) Limitations. Not for use in animals that are raised for food production. Must not be used in meat-, egg-, or milk-producing animals. The length of time that residues persist in milk or tissues has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37323, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]